

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of

HOGAN et al

Atty. Ref.: 37-55

Serial No. Unassigned

Group: 1762

Filed: November 19, 2001

Examiner: Kolb, J.

For: POWDER COATING COMPOSITION FOR ELECTROSTATIC COATING OF  
PHARMACEUTICAL...

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November 19, 2001

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

**PRELIMINARY AMENDMENT**

Please amend the above application as follows:

**IN THE CLAIMS**

Please substitute the following amended claims for corresponding claims previously presented. A copy of the amended claims showing current revisions is attached.

3. (Amended) A method according to claim 1, in which at least 30% by volume of the particles of the powder have a particle size in the range of from 5µm to 25µm.

7. (Amended) A material according to claim 5, in which at least 30% by volume of the particles of the powder have a particle size in the range of from 5 $\mu$ m to 25 $\mu$ m.

8. (Amended) A material according to claim 1, in which at least 95% by number of the particles of the material have a particle size of less than 50 $\mu$ m.

9 (Amended) A material according to claim 1, in which at least 90% by volume of the particles of the material have a particle size of at least 5 $\mu$ m.

10. (Amended) A material according to claim 1, in which the material has a resistivity, in the range of  $10^8$  to  $10^{16}$   $\Omega$ m.

11. (Amended) A material according to claim 1, which is able to be charged triboelectrically and/or by corona charging.

12. (Amended) A material according to claim 1, which is an electret or a magnet or a paramagnet.

13. (Amended) A material according to claim 1, which is susceptible to movement under the action of electrostatic forces, the susceptibility being determined

by the test defined herein.

14. (Amended) A material according to claim 1, in which the material is treatable at a temperature of less than 250 °C to form a film coating.

16. (Amended) A material according to claim 1, in which the material has a melting point in the range of 50°C to 180 °C.

18. (Amended) A material according to claim 1, in which the material exhibits a glass transition and the softening point of the material is in the range of from 30 °C to 180 °C .

19. (Amended) A material according to claim 1, in which the material comprises a polymer which is curable to form a cross-linked polymer film.

20. (Amended) A material according to claim 1, which has a moisture content (measured by moisture loss) not more than 3% by weight based on the weight of the powder coating material.

21. (Amended) A material according to claim 1, including a first component which is fusible to form a continuous film on the surface of the substrate.

23. (Amended) A material according to claim 21, in which the material includes at least 10% by weight of first component based on the weight of the material.

24. (Amended) A material according to claim 21, including a second component which is able to be charged triboelectrically.

25. (Amended) A material according to claim 21, including a second component which is an electret, or a magnet or a paramagnet.

26. (Amended) A material according to claim 21, including a second component which is susceptible to movement under the action of electrostatic forces, the susceptibility being determined by the test defined herein.

27. (Amended) A material according to claim 24, in which the second component comprises one or more of the materials in the group comprising polymers of acrylic acid and its derivatives, polyalkenes and their derivatives, polyvinyl alcohols and esters and cellulose and its derivatives.

28. (Amended) A material according to claim 24, in which the material includes at least 20% by weight of second component based on the weight of the material.

29. (Amended) A material according to claim 21, including a dispersing component for improving the dispersion of the first component and the second component.

31. (Amended) A material according to claim 29, in which the material includes at least 1% by weight of dispersing component based on the weight of the material.

32. (Amended) A material according to claim 1, including an anti—friction agent.

33. (Amended) A material according to claim 1, in which the material includes a disintegrator.

34. (Amended) A material according to claim 1, including components selected from opacifiers, colourants and flavourings.

35. (Amended) A material according to claim 1, the material including a biologically active material.

39. (Amended) A coating material according to claim 37, wherein the coating material is a powder coating material.

40. (Amended) A coating material according to claim 37, wherein at least 90%

by number of the particles of the powder have a particle size not more than 50 $\mu$ m.

42. (Amended) A method of electrostatically coating a pharmaceutical tablet core with a powder material, the powder material being according to claim 1.

45. (Amended) A method according to claim 43, in which the substrate is conveyed on a conveying means through a region adjacent to the source of powder coating material.

46. (Amended) A method according to claim 43, in which the substrate is charged when the substrate is adjacent the source of powder coating material.

48. (Amended) A method according to claim 43, in which the substrate is supported from above and the powder moves from the source upwards towards a lower surface of the substrate.

49. (Amended) A method according to claim 43, in which, before the substrate is supported adjacent to the source of powder coating material, a pretreatment composition is applied to a surface of the substrate.

52. (Amended) A method according to claim 43, in which the method further includes the step that after the surface of the substrate has been coated with the

powder, the powder is treated to form a continuous film coating secured to the substrate.

53. (Amended) A method according to claim 43, in which the method further includes the steps of supporting the coated substrate adjacent a source of powder coating material with an uncoated surface of the substrate exposed and with a surface of the substrate maintained at a different electric potential from that of the coating material whereby the application of the electric potential causes the powder to move from the source of the powder towards the substrate such that the exposed surface of the substrate becomes coated with the powder coating material.

56. (Amended) A pharmaceutical tablet comprising a tablet core and a powder coating material as claimed in claim 5.

57. (Amended) A pharmaceutical tablet that has been electrostatically coated by a method according to claim 43.

59. (Amended) A method of electrostatically coating a substrate with a powder coating material as claimed in claim 5 or as defined above.

**REMARKS**

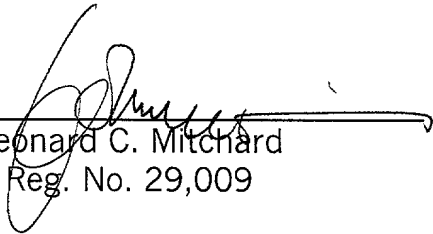
The above amendments have been made to place the application in a more traditional format.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "**Version With Markings To Show Changes Made.**"

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS**

3. (Amended) A method according to claim 1 [or claim 2], in which at least 30% by volume of the particles of the powder have a particle size in the range of from 5 $\mu$ m to 25 $\mu$ m.

7. (Amended) A material according to claim 5 [or claim 6], in which at least 30% by volume of the particles of the powder have a particle size in the range of from 5 $\mu$ m to 25 $\mu$ m.

8. (Amended) A material according to [any preceding] claim 1, in which at least 95% by number of the particles of the material have a particle size of less than 50 $\mu$ m.

9 (Amended) A material according to [any preceding claim] claim 1, in which at least 90% by volume of the particles of the material have a particle size of at least 5 $\mu$ m.

10. (Amended) A material according to [any preceding claim] claim 1, in which the material has a resistivity, in the range of  $10^8$  to  $10^{16}$   $\Omega$ m.

11. (Amended) A material according to [any preceding claim] claim 1, which is able to be charged triboelectrically and/or by corona charging.

12. (Amended) A material according to [any preceding claim] claim 1, which is an electret or a magnet or a paramagnet.

13. (Amended) A material according to [any preceding claim] claim 1, which is susceptible to movement under the action of electrostatic forces, the susceptibility being determined by the test defined herein.

14. (Amended) A material according to [any preceding claim] claim 1, in which the material is treatable at a temperature of less than 250 °C to form a film coating.

16. (Amended) A material according to [any preceding claim] claim 1, in which the material has a melting point in the range of 50°C to 180 °C.

18. (Amended) A material according to [any preceding claim] claim 1, in which the material exhibits a glass transition and the softening point of the material is in the range of from 30 °C to 180 °C .

19. (Amended) A material according to [any preceding claim] claim 1, in

which the material comprises a polymer which is curable to form a cross-linked polymer film.

20. (Amended) A material according to [any preceding claim] claim 1, which has a moisture content (measured by moisture loss) not more than 3% by weight based on the weight of the powder coating material.

21. (Amended) A material according to [any preceding claim] claim 1, including a first component which is fusible to form a continuous film on the surface of the substrate.

23. (Amended) A material according to claim 21 [or claim 22], in which the material includes at least 10% by weight of first component based on the weight of the material.

24. (Amended) A material according to [any of claims 21 to 23] claim 21, including a second component which is able to be charged triboelectrically.

25. (Amended) A material according to [any of claims 21 to 24] claim 21, including a second component which is an electret, or a magnet or a paramagnet.

26. (Amended) A material according to [any of claims 21 to 25] claim 21,

including a second component which is susceptible to movement under the action of electrostatic forces, the susceptibility being determined by the test defined herein.

27. (Amended) A material according to [any of claims 24 to 26] claim 24, in which the second component comprises one or more of the materials in the group comprising polymers of acrylic acid and its derivatives, polyalkenes and their derivatives, polyvinyl alcohols and esters and cellulose and its derivatives.

28. (Amended) A material according to [any of claims 24 to 27] claim 24, in which the material includes at least 20% by weight of second component based on the weight of the material.

29. (Amended) A material according to [any of claims 21 to 28] claim 21, including a dispersing component for improving the dispersion of the first component and the second component.

31. (Amended) A material according to claim 29 [or claim 30], in which the material includes at least 1% by weight of dispersing component based on the weight of the material.

32. (Amended) A material according to [any preceding claim] claim 1, including an anti—friction agent.

33.(Amended) A material according to [any preceding claim] claim 1, in which the material includes a disintegrator.

34.(Amended) A material according to [any preceding claim] claim 1, including components selected from opacifiers, colourants and flavourings.

35.(Amended) A material according to [any preceding claim] claim 1, the material including a biologically active material.

39.(Amended) A coating material according to claim 37 [or claim 38], wherein the coating material is a powder coating material.

40.(Amended) A coating material according to [any of claims 37 to 39] claim 37, wherein at least 90% by number of the particles of the powder have a particle size not more than 50µm.

42.(Amended) A method of electrostatically coating a pharmaceutical tablet core with a powder material, the powder material being according to [any preceding claim] claim 1.

45. (Amended) A method according to claim 43 [or claim 44], in which the

substrate is conveyed on a conveying means through a region adjacent to the source of powder coating material.

46. (Amended) A method according to [any of claims 43 to 45] claim 43, in which the substrate is charged when the substrate is adjacent the source of powder coating material.

48. (Amended) A method according to [any of claims 43 to 47] claim 43, in which the substrate is supported from above and the powder moves from the source upwards towards a lower surface of the substrate.

49. (Amended) A method according to [any of claims 43 to 48] claim 43, in which, before the substrate is supported adjacent to the source of powder coating material, a pretreatment composition is applied to a surface of the substrate.

52. (Amended) A method according to [any of claims 43 to 51] claim 43, in which the method further includes the step that after the surface of the substrate has been coated with the powder, the powder is treated to form a continuous film coating secured to the substrate.

53. (Amended) A method according to [any of claims 43 to 52] claim 43, in which the method further includes the steps of supporting the coated substrate

adjacent a source of powder coating material with an uncoated surface of the substrate exposed and with a surface of the substrate maintained at a different electric potential from that of the coating material whereby the application of the electric potential causes the powder to move from the source of the powder towards the substrate such that the exposed surface of the substrate becomes coated with the powder coating material.

56. (Amended) A pharmaceutical tablet comprising a tablet core and a powder coating material as claimed in [any of claims 5 to 40] claim 5.

57. (Amended) A pharmaceutical tablet that has been electrostatically coated by a method according to [any of claims 43 to 53] claim 43.

59. (Amended) A method of electrostatically coating a substrate with a powder coating material as claimed in [any of claims 5 to 40 or claim 58] claim 5 or as defined above.